

REMARKS

Following entry of the forgoing amendments, claims 39-77 constitute the pending claims in the present application. Claims 1-38 are hereby cancelled and replaced with claims 39-77 to more properly claim the present invention according to U.S. practice. Accordingly, the pending claims correspond to the originally filed claims as follows:

New Claim	Original Claim	New Claim	Original Claim	New Claim	Original Claim	New Claim	Original Claim
39	14	49	24	59	23	69	30
40	23	50	25	60	24	70	31
41	24	51	26	61	25	71	32
42	25	52	19	62	26	72	34
43	26	53	20	63	22	73	35
44	15	54	23	64	23	74	36
45	16	55	24	65	24	75	37
46	17	56	25	66	25	76	33
47	18	57	26	67	26	77	38
48	23	58	21	68	29		

Applicant submits that all new claims are fully supported by the disclosure as originally filed, in particular, by the claims as originally filed, and present no new matter.

I. Restriction Requirement

The outstanding Office Action, mailed May 18, 2005, identified six groups. The claims of Groups I and V, drawn to original claims 1-13 and 27, 34-37, respectively, have no corresponding claims in the pending claim set and are cancelled without prejudice. Groups II, II, IV, and VI remain and correspond to claims 39-43 and 58-62; 44-57; 63-67; and 68-77 in the pending claim set. Accordingly, Applicant hereby elects Group III, claims 44-57, drawn to a method of transplantation of cells, *with traverse*.

Applicant respectfully highlights that pursuant to MPEP 1850, "it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority." Furthermore, Examiner is kindly directed to Article 27(1) PCT, which states that:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

Applicant respectfully points out that in the instant case *neither* the International Searching Authority *nor* the International Preliminary Examining Authority found lack of unity of invention in either the International Search Report or the International Preliminary Examination Report. The apparent disregard for both the ISA's and the IPEA's finding of unity of invention under 37 CFR 1.475 evinces the impropriety of the instant restriction requirement, and Applicant requests rejoinder of the claims of Groups II-IV and VI.

In addressing the propriety of the instant Restriction Requirement, Applicant submits that the Office has misapplied the "special technical feature" standard in determining unity of invention under PCT Rules 13.1 and 13.2 and 37 CFR 1.475. In particular the Office states that the "special technical feature of group II is a method of treating type I diabetes mellitus," the "special technical feature of group III is a method of cell transplantation," the "special technical feature of group IV is treatment of blood," and that the "special technical feature of group VI is a kit." This is an overly broad and incorrect interpretation of "special technical feature." 37 CFR 1.475 states that "[t]he expression "special technical feature shall mean those technical features that define a contribution which each of the claimed inventions, *considered as a whole, makes over the prior art*" (emphasis added). The Examiner's contentions that the special technical feature of Group III is a "method of cell transplantation" or that the special technical feature of Group VI is "a kit" are not in accordance with 37 CFR 1.475 since these "technical features," as defined by the Examiner, neither attempt to define a contribution over the prior art nor consider the invention as a whole. For example, a "method of cell transplantation" generally has been described in the art, as has "a kit," "a method of treating type I diabetes mellitus," and "treatment of blood." The Office has misidentified the special technical features of the present invention.

The Examiner is also respectfully encouraged to consider the invention as a whole, particularly the surprising finding by Applicant (see, for example, p 2, lines 12-26) that the drug melagatran may be used to prevent the symptoms of instant blood-mediated inflammatory reaction (IBMIR) (Group IV). Such a discovery also contemplates that melagatran is useful in methods of transplanting insulin-producing cells, such as islets of Langerhans (Group III) and in methods of treating Type I diabetes mellitus (Group II). Of course, a method of delivery of the cells and melagatran comprising a kit (Group VI) for carrying out such methods of Groups II-IV naturally includes the same special technical features of said groups, namely the surprising utility

of melagatran in prevention of IBMIR and related applications. As such, Applicant asserts that the claims of Groups II-IV and VI all share a corresponding special technical feature according to PCT Rule 13.2 and 37 CFR 1.475 and thus possess unity of invention.

The Office has presented WO 94/29336 and Gustafson, D. et al. (*Thromb. Haemost.* 1998, 79, 110-118) and stated that these references "clearly describes [sic] the use of several small molecule compounds as useful inhibitors of serine proteases such as thrombin. Thus the technical feature is not a contribution over the prior art and hence the claims lack unity." Once again, Applicant submits that the Office has misapplied the provisions of PCT Rule 13.2 and 37 CFR 1.475 and misidentified the special technical feature. The cited references teach that melagatran is an inhibitor of serine proteases, such as thrombin. The references, neither alone nor in combination, teach or suggest the surprising utility of melagatran in the inhibition of IBMIR, and this ability could not have been predicted from the cited art. As such, the cited references do not teach or suggest the special technical feature shared by the pending claims, and this feature is a contribution over the prior art. For these reasons, Applicant requests rejoinder of the claims of Groups II-IV and VI.

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicant hereby petitions for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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Respectfully Submitted,



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